GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0230 Food; Current Good Manufacturing Practice Regulations

Dear Sir or Madam:

On behalf of the Grocery Manufacturers of America (GMA), I am pleased to submit comments to the Food and Drug Administration (FDA) on its initiative to modernize its food regulations governing current good manufacturing practices (CGMPs). GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers and sales agencies at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

Let me begin by thanking FDA for the open and participatory process it is following in considering how best to modernize its food CGMP regulations, especially at this very early stage of the agency's thinking. The food industry has enormous experience and expertise that are vital to any successful and effective revision of these regulations. GMA member companies are national and international leaders in food manufacturing and use the latest technologies and current "best practices" that bring the U.S. food supply to the highest standards of excellence.

In this regard, I was pleased to be among the speakers at the first public meeting FDA held in College Park, MD on July 19, 2004. A copy of my oral remarks are attached. As I stated we would do that day, we have conducted a detailed review of Part 110 of FDA's regulations and offer the following comments. GMA also urges that FDA continue to keep industry closely involved at each step of the process as this initiative moves forward.

Executive Summary

GMA advocates the following main points:

- **The existing CGMP regulations in 21 CFR Part 110 have worked well. Therefore, any modernization of these regulations should be carefully limited and targeted to specific areas where the current regulations can be enhanced.**
- **Any revisions to the CGMPs should follow a "general principles" approach with built-in flexibility so they may be applied across the broad spectrum of the food industry.**
- **More specific points should be addressed by FDA in guidance documents that would supplement the regulations and make specific practices easier to revise over time.**
- **Specific areas that warrant attention under this framework are: allergen control; environmental control; sanitation practices; and training.**
- **FDA should address the issue of records in a limited way.**

Introduction

For over a quarter of a century, the food CGMPs have served as the foundation for food safety in our nation's food manufacturing plants. That role is appropriate and needs to continue, adhering to the concept that CGMPs provide effective, science-based prerequisite programs for assuring food safety. Accordingly, any modernization of these regulations need to start with the premise that the current regulations have worked well, and that any revisions should be carefully limited and targeted to specific areas where the current regulations can be truly enhanced.

In identifying where to target any such revisions, GMA applauds FDA for conducting its study of food recalls[1] (hereinafter "FDA Recall Study") and for contracting with the Eastern Research Group, Inc. to conduct a broad review of the food CGMPs[2] (hereinafter "ERG Report"). Recurring topics in the ERG Report, and echoed to some extent in the FDA Recall Study, include four major areas of emphasis:

-- allergen controls, an area of increased attention throughout the food industry;

-- environmental controls, prompted largely by concerns about *Listeria moncytogenes*;

-- sanitation practices, with a particular emphasis on cleaning; and

-- employee training, which impacts the effectiveness of all areas of the CGMPs.

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[1] Food CGMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003. August 3, 2004. http://www.cfsan.fda.gov/~dms/cgmps2.html

[2] Good Manufacturing Practices (cGMPs) for the 21st Century - Food Processing, Final Report. August 9, 2004. http://www.cfsan.fda.gov/~dms/gmp-toc.html

Based on the extensive experience of GMA members, we agree these are the right topics for FDA to consider where the current CGMPs could be enhanced, and our comments below will provide recommendations in each of these topic areas.

In reviewing these specific topic areas, several themes emerge that should guide FDA's approach. The regulations should stay on the level of general principles that build in the flexibility needed to be applied across the broad spectrum of the food industry. More specific points should be addressed by FDA in guidance documents to supplement the regulations and make specific practices easier to revise over time. That is because food safety will always be dynamic. These themes—general principles, flexibility, and supplementation with guidance documents—carry throughout GMA's comments. GMA appreciates comments made at the public meetings, particularly by the Association of Food and Drug Officials (AFDO), on the need to maintain flexibility in the food CGMP regulations.

Key Topic Areas

GMA provides the following comments on the four key topic areas noted—namely, allergen controls, environmental controls, sanitation practices, and training. These are the areas where there has been the most development and change since the CGMPs were established, and, therefore, the areas where FDA can make the biggest impact in enhancing the existing food CGMPs. In addition, GMA is providing comments on the subject of records within the context of food CGMP modernization.

A. Allergen controls

One important area of greatly increased attention since the initial development of the food CGMP regulations is that of allergen control. GMA believes that the regulations should be general in nature, leaving individual companies the flexibility to implement, as appropriate to their circumstances, and providing greater detail and specificity, as needed, in a separate FDA guidance document.

The primary elements of an allergen control plan would include:

-- identification of ingredients containing food allergen(s);

-- management of these ingredients (e.g., physical segregation);

-- process controls;

-- verified cleaning processes;

-- label controls and label review; and

-- employee training.

GMA also strongly encourages FDA to develop *de minimis* levels and ultimately thresholds for individual allergens, based on the best available science. Whereas the level for some allergens, such as peanuts, may properly be very low, current science suggests that higher

levels for other allergens, such as soy, may well be justifiable. In this regard, FDA also needs to address increasingly sensitive analytical methods, not only their reliability but also the appropriate regulatory use of their results Overall, the agency needs to address whether the current zero tolerance approach, and the resulting analytical "race to zero", will provide the true balance of public health benefits and costs.

GMA believes the agency needs to include an allowance for the appropriate use of supplemental ("may contain") labeling in cases where CGMPs are completely and effectively implemented. This is especially so when the need for an allergen management program in the modernized CGMPs is placed in the context of the recent allergen labeling law.[3] For example, soy lecithin is widely used as a release agent in the baking industry. While the lecithin could contain traces of soy protein, there are no known cases of individuals allergic to soy having an adverse reaction to eating these products. However, now that the industry will be required to label these products as containing soy, these products will now be off limits to part of the population with an already limited choice of foods. GMA and its members companies will be approaching the agency to discuss these and other similar situations and ingredients, in more detail.

B. Environmental Controls

GMA recognizes that environmental controls have become an increasingly important issue within the food industry, and a significant area where industry practices have evolved since the food CGMP's were first promulgated. The goal here is to minimize the risk of finished product being contaminated with any pathogen.

1. GMA would support enhancing the food CGMP's by providing for an environmental control program based on the following general principles:
    a. Baseline sanitation program to identify and sanitize potential harborage sites;
    b. Environmental testing program to assess effectiveness;
    c. Evaluation of results and root cause analysis when positive environmental samples are found; and
    d. Corrective actions taken based on root cause analysis.
2. Any such regulatory change would need to provide the flexibility for individual food companies to administer the program as appropriate to their particular circumstances. This includes:
    a. Applying the program to different food categories, based on risk. Food companies need the flexibility to design a risk-based program. For example, products that are susceptible to contamination with a particular pathogen will need a different approach than would products which are not due to their nature, formulation and/or distribution.

[3] S. 741 Title II - Food Allergen Labeling and Consumer Protection Act of 2004. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ282.108.pdf

b. Choosing the most appropriate test and organism to address the risks. Companies need flexibility here also, for example, in choosing in the *Listeria* context whether to test for *Listeria monocytogenes* directly, or to test for *Listeria spp*. as an indicator organism. Similar programs can be implemented for target organism such as *Salmonella* in appropriate circumstances.

3. The regulations need to encourage testing and corrective action by firms without fear of regulatory repercussions. This is especially important in order to avoid providing companies with a disincentive for testing. Positive environmental findings alone should not render the surrounding product to be adulterated. Rather, positive findings should be viewed by an FDA inspector as an indicator/as evidence/as confirmation that the company is diligent. This company behavior needs to be encouraged by the regulations, not punished. The regulations should be constructed in such a way that FDA inspectors focus on the adequacy of the company's root cause analysis and corrective actions taken, not on the testing results *per se*. This is vital to the success of any new regulation in this area.

4. The specific elements of an environmental control program should be placed in a guidance document that would supplement the regulations. Elements of an environmental control program that represent current best practices in the food industry include: designing and maintaining equipment so that it can be cleaned effectively; designing production facilities so that employees and portable equipment do not spread bacteria from room to room; teaching employees to use CGMPs; making adjustments, as needed, to reflect temporary, out-of-the ordinary situations, such as construction; using sensitive detection programs to monitor the effectiveness of control systems; reassessing detection and control programs based on actual results and evolving science; evaluating and using ingredients that are bacteriostatic or bactericidal to the organism of concern; continually investigating new technologies that can be applied to packaged product to minimize the presence of the organism of concern; monitoring closely the rapidly evolving state of the science, including the availability of new analytical methods; and tailoring specific steps to a plant's environment and experiences.

C. Sanitation practices

GMA notes that implementing sound sanitation practices has always served as a foundation for CGMP programs. Going forward, the key point for FDA to focus on is how to ensure that the food CGMP regulations incorporate advances in industry practices and new technologies. The food industry has learned much over the past 20 years about the risks and causes of foodborne diseases created by the processing environment, and how those risks can be reduced.

Accordingly, GMA would support a clarification in the food CGMP regulations to expressly require food manufacturers to develop and adopt written programs outlining "good sanitation practices" they intend to follow in their manufacturing facilities. This provision should be general in nature to allow companies the flexibility to adapt such programs to their particular circumstances.

As with the closely related topics of allergen controls and environmental controls, this general mandate could reasonably be supplemented by guidance documents that incorporate advances in technology and advances in sanitation practices that have developed over the past 20 years, including: sanitary equipment design; equipment passivation; traffic controls; floor cleaning; dedicated tools and their cleaning; construction zone controls; clean-in-place and clean-out-of-place procedures; and sanitation effectiveness controls.

D. Training

The final area of preventive controls that would warrant explicit inclusion in any modernized food CGMP regulations would be training, as this area is essential to making all the other control elements effective. GMA would support a general provision on employee training modeled after the Section X of the Codex Alimentarius Code of Practice for Food Hygiene[4]. The codex standard addresses the following four areas:

-- Awareness and responsibilities;

-- Training programs;

-- Instructions and supervision; and

-- Refresher training.

Under this framework, companies would ensure that all personnel be made aware of the necessary role they themselves play in maintaining good hygiene in the workplace. Training programs would be tailored to the particular needs of the company, and would take into account a number of risk factors regarding the type of food involved and where the employee works within the facility. Finally, training and awareness would be repeated, as needed, to create sustained adherence to company procedures.

As with the other issues noted above, FDA may wish to supplement this general and flexible provision with more detailed guidance that can be more easily adjusted over time.

E. Records

The existing food CGMP regulations in Part 110 do not contain records requirements, and FDA lacks express authority in this area. Nevertheless, food companies generally do keep records to document adherence to CGMPs for their own purposes. Moreover, food companies have an exemplary history of providing FDA access to those records on a voluntary basis where there is a public health-based reason to do so. Accordingly, as FDA seeks to modernize its food CGMP regulations, GMA urges the following:

1. It is reasonable for FDA to expect food companies to maintain records needed to document adherence to CGMP's. This is current industry practice. Company

[4] Recommended International Code of Practice General Principles of Food Hygiene *CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999).* http://www.codexalimentarius.net/web/standard_list.do?lang=en

management needs those records to assure itself that its GMP program is being followed, and to defend itself should a problem ever arise.

2. Although it is reasonable for FDA to proscribe what types of records the agency believes should be maintained by food companies, the companies themselves need the flexibility to decide how those records are kept and in what form (e.g., electronically). The records are only valuable to the extent they fulfill their central purpose—to help the company monitor and assure itself of adherence to its CGMP program.

3. FDA has no statutory authority for routine access to a company's CGMP records. (*See* Appendix to GMA's comments on FDA's BSE-related recordkeeping proposed rule, submitted to the agency on August 16, 2004, entitled: "FDA Has No General Authority Under the Federal Food, Drug and Cosmetic Act to Require Manufacturers of Food or Cosmetics to Disclose Company Records to FDA Inspectors"). Furthermore, FDA does not need such access.

4. It is reasonable for FDA to request voluntary access to a company's CGMP records when a real problem has been identified. History has shown that, when a genuine public health need has been identified (e.g., FDA has reports of an illness that may be associated with a company's product), the food industry has an exemplary record of voluntarily providing reasonable access to pertinent records and working cooperatively with the agency in this regard. However, GMA opposes any records access requirements in the absence of express legal authority.

5. The product would not become or be considered adulterated or misbranded due to any recordkeeping deficiencies *per se*. Rather, FDA should need to find the CGMP program itself to be deficient such that product is being produced under insanitary conditions (or the underlying product or its labeling to be adulterated or misbranded) before FDA could initiate regulatory action. In this way, the remedial focus of the CGMP regulations should be on the adequacy of the CGMP program itself, not on the records alone.

Responses to FDA's Questions

In its notices of public meetings[5] on this subject, FDA posed a general question, and 11 more specific questions, to which GMA offers the following responses.

Q. In general, do the current good manufacturing practice regulations (part 110) need to be revised or otherwise modernized? If yes, please describe generally the shortcomings of the current regulations.

The existing food CGMP regulations in 21 CRF Part 110 have worked very well and have withstood the test of time. FDA should approach this modernization effort with that in mind, and should identify only those targeted and particular areas where the food CGMPs could be enhanced, within their existing framework. As noted above, GMA believes the food CGMPs could be enhanced in the specific areas of food

[5] 69 FR 29220, May 21, 2004; 69 FR 40312, July 2, 2004.

allergens, environmental controls, sanitation programs and training, as well as a limited and carefully circumscribed provision on records.

1. *Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?*

   The strength of the food CGMPs is that they are broad-based and flexible so they can be applied across the entire food industry as appropriate to particular circumstances. Conversely, the area(s) where the CGMPs are least effective are where they are too prescriptive, such as the specific temperature requirement in 21 CFR 110.80 to maintain refrigerated foods at 45º F (7.2 ºC) or below, and maintaining hot foods at 140º F (60 ºC) or above. For example, the refrigeration temperature is handled differently in the Pasteurized Milk Ordinance (PMO) and the model Food Code, so affected products face differing standards. For a regulation as broad as the food CGMP, it would be preferable to require temperature control to be "adequate" to control bacteria for the particular product, and leave specific temperature recommendations to product- and/or process-specific guidance documents.

2. *In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?*

   One of the biggest contributors to administering a sound CGMP program is the challenge presented in training a diverse work force. This is particularly true where language barriers exist. Greater use of food safety icons is one step that would help in this regard, and the food safety icons developed by the International Association for Food Protection are increasingly being used.[6]

3. *If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?*

   It is not clear that any hazards can be totally prevented by CGMP controls, but CGMPs can help reduce the likelihood of hazards occurring. As noted above, post-processing contamination by pathogens could be reduced through implementation of an environmental control program. Mislabeling with respect to food allergens is a second example where problems could be reduced.

4. *Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.*

   The major examples of where the current food CGMP regulations could be enhanced would be in the areas of: allergen control; environmental control; sanitation programs; and training. *See* recommendations described above.

[6] http://www.foodprotection.org/

5. *What concepts or underlying principles should guide FDA's adoption of newer preventive controls?*

   The first principle is that FDA should keep the existing CGMP regulations as the foundation, and enhance those regulations only in targeted ways.

   The second principle is that those enhancements should stay at the "general principles" level so companies retain the flexibility needed to apply the regulations to their particular circumstances in the most effective and efficient way.

   The third principle is that specific or technical issues should be addressed in guidance documents that can more easily evolve through time, as science and industry practices evolve.

   The fourth and final principle is that the CGMPs should reflect the current "best practices" within the food industry, and so the food industry itself needs to be closely involved with FDA at every step of these proceedings.

6. *How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?*

   FDA should use its existing categorization of facility inspections to measure the effectiveness of the CGMP regulations. As the agency is well aware, the results of each FDA inspection are reviewed and classified in one of three ways: No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI).

   FDA should use, as its primary barometer, the number of firms that fall into the third category, or OAI, because FDA considers these firms to be out of compliance and subject to regulatory action. Over time, the number of firms in this category should decrease if the regulation is being implemented successfully.

   FDA should also use, as a secondary barometer, the number of firms that improve from a VAI classification—which means a level of problems that the company would be expected to fix by the next inspection—down to the NAI classification. This type of comparison would need enough time for FDA to conduct repeat inspections of the same firms.

7. *In today's manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?*

   Although GMA does not have specific data on this point, the general experience of our members suggests that labeling errors account for a substantial majority of food allergen problems, and that cross-contamination during manufacturing account for a much lesser number. Addressing both of these issues could be improved by including an explicit requirement in the CGMPs for an allergen control program within the manufacturing facility.

As noted above, it would also be most useful if FDA could address the issue of thresholds for the major food allergens. Establishing biologically relevant levels for food allergens, that are scientifically supportable, would go a long way towards providing food companies with a clearer target of what they need to achieve. There is always concern that "chasing zero" is neither cost-effective nor necessarily needed for effective consumer protection.

8. *Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food CCGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort?*

GMA believes that FDA's own food CGMP regulations should remain the basis for any modernization effort, and that those regulations should be enhanced in targeted areas rather than rewritten or reconstituted.

Within that framework, FDA should consider the Codex Alimentarius Code of Practice for Food Hygiene as a model for setting standards at the "general principles" level, as GMA has recommended FDA do. Section X of that standard referenced earlier, dealing with training, provides an excellent reference for potential training requirements as well as an excellent template for more general applicability. FDA should also consider an industry guidance document developed by the Food Allergy Issues Alliance.[7] This guidance document addresses primarily labeling controls, and its value to FDA would be both for its substantive contribution as well to illustrate the value of guidance documents that go beyond the regulations themselves.

9. *There is broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?*

GMA urges that FDA **not** try to develop separate CGMPs for different segments of the food industry. Rather, the strength and primary value of the current CGMPs that have worked so well is their umbrella framework and ability to be applied across broad and diverse segments of the food industry. To the extent that FDA seeks to provide more specific direction to a particular segment of the food industry, the agency should work directly with that industry segment to develop guidance applicable to them.

Should FDA choose to amend its CGMP regulations, GMA does recognize that it is reasonable to provide more time to small businesses to implement them, as many small companies simply do not have the resources of most GMA members to adopt

[7] Food Allergy Issues Alliance Labeling Guidelines
http://www.gmabrands.com/news/docs/Testimony.cfm?docid=768&

and implement new regulations within their facilities in a short period of time. This is the same approach the FDA has taken in other rulemakings affecting large numbers of small businesses.

10. *There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:*

- *Training programs for managers and/or workers;*
- *Audit programs;*
- *Written records, e.g., batch records, sanitation records;*
- *Validation of control measures;*
- *Written sanitation standard operating procedures;*
- *Food label review and control programs;*
- *Testing of incoming raw materials, in-process materials, or finished products.*

Which (if any) of these should be required practices for food manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?

As explained above, GMA believes that most valuable enhancements to the existing CGMP regulations would be to add general requirements for allergen control, environmental control, sanitation programs and training. GMA would also support limited and carefully circumscribed regulations governing records. These are the primary areas referenced in the FDA Recall Study and the ERG Report as areas warranting more attention in recent years, and this is consistent with the experience of many GMA members.

The remaining topics—and more specific elements of these broader topics—are best left on a voluntary basis because the effective application of them varies so much from company to company and from product area to product area that trying to bring them under a single, prescriptive regulatory scheme is simply not desirable or feasible. These include: audits programs; validation of control measures; sanitation standard operating procedures; food label and control program (outside of food allergen controls); and testing of incoming raw materials, in-process materials, or finished products.

11. *Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehouses that are needed to help ensure the safe and sanitary holding of food. If yes, please identify the controls by hazard and sector of the industry.*

The current food CGMPs when applied are adequate and effective in this regard.

Conclusion

GMA thanks the FDA for providing this opportunity to comment on the agency's effort to modernize the food CGMP regulations. GMA would support targeted and carefully focused revisions to the existing regulations that have worked so well for over 20 years. Such revisions

to the regulations should remain general in nature to provide food companies needed flexibility and should be limited to areas where updating is truly necessary. More specific and technical information should be contained in guidance documents that are developed in concert with the many experts in the food industry.

GMA and its member companies look forward to continuing to work with FDA under this framework in the months and years ahead.

Respectfully submitted,

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